Medtronic

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5954 '00 OCT -6 A7:56

August 14, 2000

Russ Pagano, PhD
Office of Device Evaluation
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Re: Request Presentation as part of Administrative Record

Dear Mr. Pagano:

This correspondence is to formally request submission of the attached copies of overheads into the administrative record. The overheads are from the meeting "Reclassification of IPG for Chronic Pain," held on July 27, 2000

If you have any questions regarding this request, please contact the undersigned.

Sincerely,
MEDTRONIC NEUROLOGICAL

Kathy J. Fahey

Principal Product Regulation Manager

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When Life Depends on Medical Technology

Reclassification of IPG for Chronic Pain

July 27, 2000

Representatives

- Richard Simpson, MD - Associate Professor of Neurosurgery, Physical Medicine and Rehabilitation and Anesthesiology, Baylor College of Medicine
- Cliff Owens – VP/GM of Neurostimulation
- Lynn Switzer – Director, RA,QA and Clinical
- Amanda Klosterman – Sr. Legal Counsel
- Kevin Kelly – Director, Product Development
- Kathy Jo Fahey – Principal Product Regulation Manager
- Mark Heller – Hale and Dorr LLP, Legal Counsel

Objective

- Review the content of the communication dated 1-31-00
- Discuss the inappropriateness of reclassification of IPGs into class II

Five Main Points

- The 1st point:
  - The petitioner has not demonstrated that Class III controls are unnecessary to reclassify the device in order to provide reasonable assurance of the safety and effectiveness of the device.
- The 2nd point:
  - The petitioner has failed to provide sufficient valid scientific evidence to demonstrate that Class II controls can provide a reasonable assurance of safety and effectiveness.

- **Point 3:**
  - Due to the irregularities in the proceedings the Panel was misinformed.
- **Point 4:**
  - FDA's use of Medtronic's PMA data to consider reclassification of IPGs would be illegal.
- **Point 5:**
  - FDA has ruled as recently as 1995 that the totally implantable spinal cord stimulator is a Class III, PMA device.

DEPARTMENT OF HEALTH & HUMAN SERVICES - Public Health Service

DEC 29 1995 '00 OCT -6 A7:56

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert J. Klapinski
Senior Legal Counsel
Medtronic, Inc.
Law Department
7000 Central Avenue, NE
Minneapolis, Minnesota 55432-3576

Re: C950010 — Classification of Medtronic Itrel™
Dated: November 22, 1995
Received: December 20, 1995

Dear Mr. Klapinski:

This is response to your request to Mr. Fred Sadler for classification information dated November 22, 1995. The Medtronic Itrel™ Totally Implantable Spinal Cord System was determined by PDA to be a class III device by order dated October 29, 1980, (copy enclosed). The Food and Drug Administration (FDA) determined that the Medtronic Totally Implantable Spinal Cord System was not substantially equivalent to any device marketed prior to May 28, 1976, or to any device classified as a class I or class II device; therefore it could not be marketed until FDA approved a premarket approval application in accordance with Section 513(f) of the Federal Food, Drug, and Cosmetic Act.

As specified by Section 513(f) of the Food, Drug, and Cosmetic Act (act), a device to be marketed after May 28, 1976, is classified into class III unless the FDA determines the device to be substantially equivalent to a preamendments device, or the device is reclassified into class I or class II.

FDA determined that this Medtronic device was not substantially equivalent to devices classified in Title 21, Code of Federal Regulations, Section 882.5880 (21 CFR 882.5880) based on significant technological differences. For example, the Medtronic device employs an implanted device containing a power source; whereas, the devices classified in 21 CFR 882.5880 employs an implanted device comprised entirely of passive components with necessary energy being provided by an external device.

As further evidence of this determination, FDA sent to Medtronic, Inc. on August 2, 1989, an order approving the Premarket Approval Application (PMA) for the Medtronic Itrel II™, which includes a Model 7424 Implantable Pulse Generator and a Model 7496 Quadrapolar Extension.

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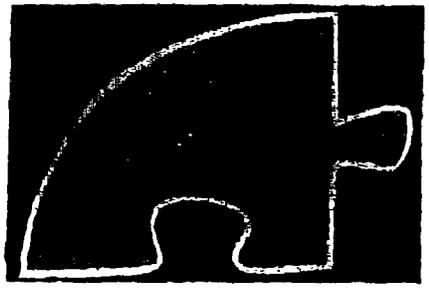
We believe this unequivocally establishes that Medtronic Totally Implantable Spinal Cord System is by statute a class III device for which an approved PMA is required for marketing. If you have further questions, please contact Robert F. Munzner, Ph.D., at (301) 443-8517.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MFG
VALIDATION
PATIENT SAFETY
DESIGN



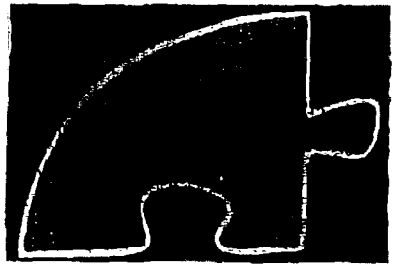
Manufacturing is the key to maintaining safety over the life of an IPG device. It defines the performance and the reliability of an IPG. Also, it is critical for characterizing the device and to ensure it's made in a predictable and reproducible way.

- For a Class III PMA device: A "pre-approval" inspection is required for new devices including auditing MFG & quality systems. Bi-annual visits also occur.
- For a Class II 510(k) device: No MFG evidence is required. The post approval inspection is "After the fact", and subsequent follow up inspections are less frequent than bi-annual visits with Class III.

* (Note: It was the pre-approval inspection of Neuromed (ANS) TIME device (neurostimulator) that uncovered patient injury issues (battery leakage, overstimulation) and prevented market release of an unsafe product.)

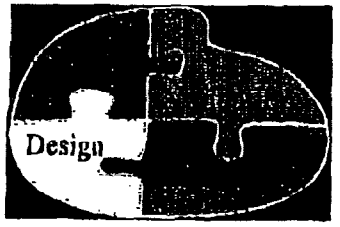
Failure Mode and Effect Analysis Comparison

Failure Mode		IPG Effect Class III	RF Effect Class II	Example(s)
Antenna Failure	Open / Shorted	- Unable to Communicate with Device - Unable to Adjust Stimulation for Posture - Patient May be in a disabled state until explanted *Patient Injury* (Replace IPG)	No Stimulation (Fail Safe) (Replace Receiver or Antenna)	MFG Defects: - Cold solder joint - Broken wire bond - Contamination on printed circuit board
Battery or Power Source Failure (Mechanical)	Weld Failure F/T Failure Puncture	- Battery Chemical Leaks into IPG: Damage to Electronics - Damage to IPG Feedthrough and Chemical Leakage to Body Resulting in Tissue Damage *Patient Injury*	Not Applicable Replace Transmitter (Fail Safe)	MFG Defect: - Weld failure - Feedthrough failure



The following are a few examples of the many processes that Medtronic considers confidential or trade secret and are key to reliable manufacturing of implanted medical device.

- Feedthrough Welding
- Hermetic Seam Welding
- Feedthrough Preparation
- Battery Welding
- Wire bonding and component interconnect



Summary

- There are several pieces of the puzzle that come together to ensure medical device safety.
- Re-classification weakens the puzzle by relying on substantial equivalence and delaying or omitting pieces of the puzzle ("pre-approval" inspection, clinical validation).
- There are risks with each new device and each new manufacturer. Pre-Market Approval (Class III) has the controls in place that maximize detection of a risk/hazard to patient safety "Before" the product is released to the market.
- Medtronic is the only supplier of fully implantable neurostimulators. Other suppliers will be able to do it also, but the FDA doesn't have the data to ensure they know how to do it. No manufacturing information or original clinical data was supplied with petition, and assuming reclassification no data will be available through the 510(k) process until after market release.

Failure Mode		IPG Effect Class III	RF Effect Class II	Example(s)
Battery or Power Source Failure (Electrical)	Open	No Stimulation (Fail Safe) (Replace IPG)	No Stimulation (Fail Safe) (Replace Transmitter)	MFG Defect: - Poor mechanical connection
	Shorted	Example Feedthrough short: - IPG Heating - Damage to Electronics - Damage to IPG Feedthrough and/or Chemical Leakage to Body Resulting in Tissue Damage *Patient Injury*	Replace Transmitter Battery (Fail Safe)	MFG Defect: - Contaminated feed through - Ruptured insulator
Stimulation Control Circuitry Failure (Hybrid or Circuit failure)	Open/Shorted	No Stimulation (Fail Safe) - Excessive Current Drain IPG Heating until Battery Depletion. - Undesirable or Over-Stimulation *Patient Injury*	No Stimulation (Fail Safe) Remove External Antenna (Fail Safe) Replace Transmitter (Fail Safe)	MFG Defect: - Contamination on printed circuit board - Defective component or connection. - Cold solder joint

Conclusion: Manufacturing defects in an IPG result in a greater risk to patient safety than the same defects in an RF device.

Discussion